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| TRANSMITTAL LETTER TO THE UNITED STATES<br>DESIGNATED / ELECTED OFFICE (DO/EO/US)<br>CONCERNING A FILING UNDER 35 U.S.C. 371 |   | ATTORNEY'S DOCKET NUMBER<br><b>P65141US0</b>                      |
| INTERNATIONAL APPLICATION NO.<br><b>PCT/EP98/05899</b>   | INTERNATIONAL FILING DATE<br><b>16 September 1998</b> | US APPLICATION NO. (If known, see 37 CFR 1.5)<br><b>09/508095</b> |
| TITLE OF INVENTION<br><b>BIFIDOGENIC PEPTIDES</b>  |   | PRIORITY DATE CLAIMED<br><b>16 September 1997</b>                 |
| APPLICANT(S) FOR DO/EO/US<br><b>Hans-Dieter ZUCHT -and- Cornelia LIEPKE</b>  |   |   |

**Applicant herein submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information.**

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4. ☒ A proper Demand for Internatl. Preliminary Examination was made by the 19th month from earliest claimed priority date.
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
  - a. ☐ is transmitted herewith (required only if not transmitted by the International Bureau).
  - b. ☒ has been transmitted by the International Bureau.
  - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US)
6. ☒ A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
  - a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
  - b. ☐ have been transmitted by the International Bureau.
  - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
  - d. ☒ have not been made and will not be made.
8. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☒ A translation of the annexes to the Internatl. Preliminary Examination report under PCT Article 36 (35 U.S.C. 371(c)(5)).

**Items 11. to 16. below concern other document(s) or information included:**

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☒ An assignment document for recording. A separate cover sheet compliance with 37 CFR 3.28 and 3.31 is included.
13. ☒ A **FIRST** preliminary amendment.  
☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
14. ☐ A substitute specification.
15. ☐ A change of power of attorney and/or address letter.
16. ☒ Other items or information:
  - International Search Report — EPO
  - PCT/IB/301 Form
  - PCT/IB/304 Form
  - PCT/IB/308 Form
  - First Page of Publication
  - International Preliminary Examination Report — with Annexes in German
  - Small Entity Declaration
  - Sequence Listing in German

|   |                     |   |             |   |    |
|---|---------------------|---|-------------|---|----|
| US APPLICATION NO. (If known, see 37 CFR 1.51)<br><div style="font-size: 2em; font-weight: bold; margin-left: 100px;">097/5085</div>  |                     | INTERNATIONAL APPLICATION NO.<br><div style="font-weight: bold; margin-left: 100px;">PCT/EP98/05899</div> |             | ATTORNEY'S DOCKET NUMBER<br><div style="font-weight: bold; margin-left: 100px;">P65141US0</div> |    |
| 17. <input checked="" type="checkbox"/> The following fees are submitted:<br><br><b>Basic National F (37 CFR 1.492(a)(1)-(5)):</b><br>Internat'l. prelim. examination fee paid to USPTO (37 CFR 1.492 (a) (1)) ... \$670.00<br>No international preliminary examination fee paid to USPTO (37 CFR 1.492 (a) (2)) but international search fee paid to USPTO (37 CFR 1.445(a)(2)) ... \$760.00<br>Neither international preliminary examination fee (37 CFR 1.492 (a) (3)) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO) ..... \$970.00<br>International preliminary examination fee paid to USPTO (37 CFR 1.492 (a) (4)) and all claims satisfied provisions of PCT Article 33(2)-(4) ..... \$96.00<br>Search Report prepared by the EPO or JPO (37 CFR 1.492 (a) (5)) ..... \$840.00<br><br><div style="text-align: right;"><b>ENTER APPROPRIATE BASIC FEE AMOUNT =</b></div> |                     |   |             | CALCULATIONS<br><br><br><br><br><br><br><br><br><br>\$ 840.00                                   |    |
| Surcharge of \$130.00 for furnishing the oath or declaration later than<br><input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(e)).  |                     |   |             | \$  |    |
| <b>Claims</b>   | <b>Number Filed</b> | <b>Number Extra</b>   | <b>Rate</b> |   |    |
| Total Claims  | 4 - 20 =            | -0-   | x \$18.00   | \$  |    |
| Independent Claims  | 1 - 3 =             | -0-   | x \$78.00   | \$  |    |
| Multiple Dependent Claim(s) (if applicable)   |                     |   | + \$260.00  | \$  |    |
| <b>TOTAL OF ABOVE CALCULATIONS =</b>  |                     |   |             | \$ 840.00   |    |
| Reduction by 1/2 for filing by <b>small entity</b> , if applicable. Verified Small Entity statement must also be filed. (Note 37 CFR 1.9, 1.27, 1.28).  |                     |   |             | \$ 420.00   |    |
| <b>SUBTOTAL =</b>   |                     |   |             | \$ 420.00   |    |
| Processing fee of \$130 for furnishing the <b>English translation</b> later than<br><input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(f))  |                     |   |             | \$  |    |
| <b>TOTAL NATIONAL FEE =</b>   |                     |   |             | \$ 420.00   |    |
| Fee of \$40.00 for recording the enclosed <b>assignment</b> (37 CFR 1.21(h)). Assignment must be accompanied by appropriate cover sheet (37 CFR 3.28, 3.31).  |                     |   |             | \$ 40.00  |    |
| <b>TOTAL FEES ENCLOSED =</b>  |                     |   |             | \$ 460.00   |    |
|   |                     |   |             | <b>Amt. to be refunded:</b>   | \$ |
|   |                     |   |             | <b>Amt. charged:</b>  | \$ |
| a. <input checked="" type="checkbox"/> A check in the amount of \$ <u>460.00</u> to cover the above fees is enclosed.<br><br>b. <input type="checkbox"/> Please charge my Deposit Account No. <u>06-1358</u> in the amount of \$ <u>---</u> to cover the above fees. A duplicate copy of this sheet is enclosed.<br><br>c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge my account any additional fees set forth in §1.492 during the pendency of this application, or credit any overpayment to Deposit Account No. <u>06-1358</u> . A duplicate copy of this sheet is enclosed.  |                     |   |             |   |    |
| SEND ALL CORRESPONDENCE TO:<br><b>Jacobson, Price, Holman &amp; Stern, PLLC</b><br>400 7th Street, N.W., Suite 600<br>Washington, DC 20004<br>202-638-6666<br><b>CUSTOMER NUMBER: 00136</b>   |                     |   |             | By<br>William E. Player<br>Reg. No. 31,409  |    |

Attny's Docket No. \_\_\_\_\_

**SMALL ENTITY DECLARATION**  
[37 CFR 1.9(c-f)]

Each undersigned declares that:

(1) ☐ the application attached hereto.

(2) ☐ U.S. Application Serial No. \_\_\_\_\_, filed \_\_\_\_\_

(3) ☐ U.S. Patent No. \_\_\_\_\_ Issued \_\_\_\_\_

is entitled to the benefits of "small entity" status for paying reduced fees under 35 USC 41(a) and (b) to the Patent and Trademark Office by virtue of the following:

(4) ☒ Each undersigned declares that he/she qualifies as an independent inventor, or would qualify had he/she made the invention, as defined in 37 CFR 1.9(c).

(5) ☐ The undersigned declares that he/she is an official empowered to act on behalf of the concern identified below; that this concern qualifies as a small business concern as defined in 37 CFR 1.9(d); that exclusive rights to the invention have been conveyed to and remain with the small business concern, or if the rights are not exclusive, that all other rights belong to small entities as defined in 37 CFR 1.9.

(6) ☐ The undersigned declares that he/she is an official empowered to act on behalf of the organization identified below; that this organization qualifies as a nonprofit organization as defined in

(a) ☐ 37 CFR 1.9(e)(1)

(b) ☐ 37 CFR 1.9(e)(2)

(c) ☐ 37 CFR 1.9(e)(3)

(d) ☐ 37 CFR 1.9(e)(4) State law of \_\_\_\_\_

that exclusive rights to the invention have been conveyed to and remain with the organization, or if the rights are not exclusive, that all other rights belong to organizations as defined in 37 CFR 1.9.

(7) Each person, concern or organization to which I/we have assigned, granted, conveyed or licensed, or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

(a) ☐ no such person, concern or organization

(b) ☐ persons, concerns or organization listed below

[a separate declaration is required from each named person, concern or organization having rights to this invention averring to their status as "small entities."]

Full Name \_\_\_\_\_

Address \_\_\_\_\_

☐ Individual

☐ Small Business Concern

☐ Nonprofit Organization

I/we acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement of small entity prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I/we hereby declare all statements made herein of his/her own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application, any patent issued thereon, or any patent to which this declaration is directed.

(8) Prof. Dr. Wolf-Georg FORSSMANN Wolff 22/02/2000  
Typed Name of Inventor Signature Date

\_\_\_\_\_  
Typed Name of Inventor Signature Date

\_\_\_\_\_  
Typed Name of Inventor Signature Date

\_\_\_\_\_  
Typed Name of Inventor Signature Date

(9) \_\_\_\_\_  
Name of Small Business Concern or Nonprofit Organization

\_\_\_\_\_  
By Signature Date

\_\_\_\_\_  
Title of Signatory

## INSTRUCTIONS FOR THE COMPLETION OF SMALL ENTITY DECLARATION

Check box (1) if for use with application about to be filed.

Check box (2) or (3) if for use with application already on file or Patent and complete U.S. Serial No. and Filing Date, or Patent No. and issue date, if known.

CHECK ONLY ONE OF BOXES 4, 5 OR 6, WHICHEVER IS APPLICABLE

Check box (4), individuals who are either: (a) an inventor or (b) a person who would qualify as an independent inventor had he/she made the invention, must sign and date at (8), if he/she have not, and are under no obligation to assign, grant, convey or license any right in the invention to any person who could not likewise be classified as an independent inventor if that person had made the invention or to any concern which would not qualify as a small business concern or non-profit organization (see below).

Check box (5), date, complete name of small business concern and authorized signatory, sign and complete his/her title at (9), if small entity status is claimed by virtue of inventor(s) rights having been, or being obligated to assign, grant, convey or license, to a concern whose number of employees, including those of its affiliates, does not exceed 500 persons. Concerns are affiliates when either controls, directly or indirectly, or has the power to control, the other, or a third party has the power to control both. Number of employees is average over fiscal year of those employed during each pay period, including full-time, part-time or temporary employees. If the small business concern has or is under obligation by contract or law to transfer any rights to another who cannot qualify as small entity, then small entity status not applicable.

Check box (6) and subsection (a), (b), (c) or (d), date, complete name of the nonprofit organization and authorized signatory sign and complete his/her title at (9), if small entity status is claimed by virtue of inventor(s) rights having been, or being obligated to, assign, grant, convey or license, to a nonprofit organization. Subsection (6)(a) to be checked if organization is university or other institution of higher learning; (6)(b) to be checked if organization of type described in Section 501(c)(3) of IRS Code and exempt from taxation under Section 501(a); (6)(c) to be checked if organization is nonprofit scientific or educational organization qualified under a statute of State of the U.S.; and (6)(d) to be checked if foreign organization and would qualify under (6)(b) or (6)(c) if such organization was located in the U.S.A. Fill in the State law under which the organization would qualify.

Check box (7)(a) or (b) as the facts dictate.

### IMPORTANT

(1) Note that U.S. lawyers and agents cannot complete this document after signed. Therefore please completely fill it in before sending to us.

(2) Each person, concern or organization that has an interest in this invention must sign one of the "Small Entity" Declarations. For example, if an inventor/employee has an obligation to assign to his employer, a corporation having fewer than 500 employees, which corporation has licensed this invention to a licensee corporation also having less than 500 employees, then three "Small Entity" declarations are necessary before the lesser fee can be paid: one from the inventor; one from an official of the employer; and one from an official of the licensee. In the declarations by the inventors and the employer paragraph 7(b) would have to be checked and filled in, the licensee would check paragraph 7(a).

We will be pleased to answer your questions. You may contact us in the following ways:

### JACOBSON, PRICE, HOLMAN & STERN, PLLC

TELEPHONE: (202) 638-6666  
TELFAX: (202) 393-5350  
(202) 393-5351  
(202) 393-5352  
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